

Heller Ehrman White & McAuliffe LLP  
Attorney Docket No. 37794-0032

U.S. Serial No. 09/986,344  
Peter Law.

### REMARKS

Claims 33-51 are pending before entry of this amendment. In response to the office action mailed May 24, 2005, applicant amends the claims and provides arguments for patentability over the cited references. The term "pure culture" added to the claims is supported by the claims throughout, for example on page 9, line 33. Amendments have not added new terms and no new matter has been added.

Reconsideration and allowance of the claims are courteously solicited.

#### Objection to the Specification

The examiner has objected to the specification because the status of application 08/477,377 has changed. In response the suggested correction has been made.

#### Claim Rejections 35 USC 112

Claims 34-36 and 43-45 stand rejected on alleged indefiniteness grounds. Applicant points out that the term "the" used in claims 34 and 43 refers to the preceding (earlier presented) "patient" in claims 33 and 42, respectively. That is, applicant refers to a new subject using "a" and then when referring back to that subject, uses the term "the." Applicant believes that the claims are clearer with "the" referring back to the subject in the independent claims because the dependent claims should always be read together with their independent claim precedents.

In Claims 42 and 43, the applicant amended to read "a human donor" and "a human donor's" respectively as suggested by the examiner.

Reconsideration and allowance are requested.

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Rejection of claims 33-51 on alleged obviousness grounds

Wu has been combined with 6 other references in an obviousness rejection. Applicant points out that, on the one hand, motivation to combine these six references is not stated in the office action, and on the other hand, (see page 5 lower middle) the Examiner has argued that the applicant has not argued against this supposed motivation "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references."

Applicant has amended the claims to bring them in condition for allowance several ways.

One, applicant has argued that animal work on other cell types, (which differ from that claimed), for transplantation into other locations, (which differ from that claimed), does not obviate the claimed invention. Applicant points out in this respect that the cell quality and number is extremely important and that in particular, the use of very pure cells that lack appreciable fibroblast growth is of utmost importance. The animal studies failed to appreciate this. Until now, applicant has not had this distinction as a claim feature.

As explained before, the purity of the procedures referenced for humans generally is at or above 99% with respect to contaminating fibroblasts. Those procedures and the quality of cells, are cited in the reference on page 9, lines 34-36 which provides "a pure culture." A skilled artisan in this field reading that reference understands and appreciates this difference. This limitation has been added as the term "a pure culture" to claims 33 and 42. The Examiner argues on the top of page 5 of the office action that the specification does not indicate that the term "patient" refers specifically to human subjects. The specification indicates on page 9 lines 18-20 that an "other animal donor" is a different species from that of "a patient." To make this more clear in the claims, applicant has amended them to specifically recite humans, in order to bring the claims in condition for allowance.

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This big difference from the animal studies further distinguishes the invention and bring the claims in condition for allowance.

Reconsideration and allowance are requested.

Two, applicant has added features that were argued as distinguishing the invention, to the claims, in response to the Examiner's mention that "the features upon which applicant relies are not recited in the rejected claim(s)." (page 5, bottom). To put the claims in condition for allowance, the term "in a form that allows fusion with and intracellular expression in pre-existing muscle cells of the human patient" has been added to claim 33, and the term "in a form that allows fusion with and intracellular expression in pre-existing muscle cells or fat cells of the human patient" has been added to claim 42. The Examiner's argument on page 6 middle that "claim 42 does not embrace the use of fat cells" is addressed by this amendment, which specifically refers to such fusion, and thus places the claims in better condition for allowance. Applicant points out that the term "in a form that allows fusion" is very important, and had to discover the proper use of chondrotin for this purpose. Such "form that allows fusion" sufficiently to work, was not available in 1994 when Wu published his paper.

Applicant points out that an inherent and very desirable feature of the claimed invention is that myoblasts fuse with pre-existing muscle cells and continuously express within those cells. Upon stress, the peptide comes out of the cells more readily. The added language is a major distinction from the animal studies and places the claims in better condition for allowance. The term "human" has been added to ensure that a skilled worker reading the claims can understand this more clearly.

Reconsideration and allowance are solicited.

Three, special methods that pertain particularly to human clinical use (as distinct from animal experiments), namely the sampling, grow up and use of autologous cells

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from the patient is emphasized (claim 33, as described in the examples) to further distinguish the claimed invention and place the claims in condition for allowance.

Reconsideration and allowance are requested.

Applicant submits a copy of a recent publication that summarizes the state of the art of myogenic cell therapy. This publication shows the advances made by applicant generally and focuses on cardiovascular disease rather than in pain therapy, because the former problem is addressed first due to the urgency of this highly prevalent disease. These related data are in the heart repair area.

Respectfully submitted,

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